

Great Earth®

VITAMIN STORES

March 21 2003

3960 03 MAR 27 10:12

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Dear Sir or Madam;

My husband & I own a vitamin & nutritional supplement store in Louisville, KY, and have been in the natural products industry for over 10 years. Both my customers and I appreciate how the passage of the Dietary Supplement Health & Education Act of 1994 improved consumer access to dietary supplements and information about them, while increasing consumer protection against unsafe products and false and misleading claims.

We are concerned however that the FDA has only just begun to initiate aggressive enforcement actions under DSHEA, yet is calling for suggestions for increased legislative authority in order to better regulate the supplement industry. Shouldn't you first give these recent efforts a chance to work? And perhaps even issue good manufacturing practices for supplements before calling for new laws?

We believe that the FDA can regulate ephedra sales without dismantling DSHEA.

It is also my understanding that DSHEA increased the FDA's enforcement powers and that the FDA can seize a dietary supplement if it presents an unreasonable or significant risk of illness or injury. Furthermore, the government can stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard.

The former FDA commissioner, Dr. Jane Henney, has stated before Congress that she believes that DSHEA provides FDA with the necessary legal authority to protect the public health. I agree with Dr. Henney, strongly support DSHEA, and do not think any additional legislative authority is necessary.

Sincerely,

Carol

Carol Rudolph

95N-0304

C3800